



INVESTOR IN PEOPLE

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Your Reference: P33587GB1/TF/LJP
Application No: GB 0313086.1

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24 March 2004

Dear Sirs

Patents Act 1977: Examination Report under Section 18(3)

Latest date for reply: 26 July 2004

I have re-examined your application in response to your agent's letter of 20 February 2004 and enclose two copies of my further examination report.

By the above date you should either file amendments to meet the objections in the enclosed report or make observations on them. If you do not, the application may be refused.

Yours faithfully

Dr William Thomson
Examiner

**CERTIFIED COPY OF
PRIORITY DOCUMENT**

[†]Use of E-mail: Please note that e-mail should be used for correspondence only.



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Patents Act 1977 Examination Report under Section 18(3)

Basis of the examination

1. My examination has taken account of the amendments filed with your agent's letter of 20 February 2004.

Inventive step

2. The invention as defined in claims 1-12 is obvious in view of what has already been disclosed in the following documents:

(a) EP 0904784A1 (N.V.NUTRICIA); vs claims 1-12; See whole document, in particular column 8, line 27-33, Examples 6-8 and claims 1-3 and 14.

(b) WO 97/35596A1 (ABBOT LABORATORIES); vs claims 1-12; See whole document, in particular page 4, line 17 - page 5 , line 1.

(c) WO 01/01/58465A2 (REID ET AL); vs claims 1-12; See whole document, in particular page 6, line 18 - page 8, line 15 and page 8, lines 26-29.

(d) WO 01/098516A3 (REGENTS OF THE UNIVERSITY OF MINNESOTA); vs claims 1-12; See whole document, in particular page 13, line 33 - page 14, line 18 and the Examples.

3. The inventive step objection is sustained with regard to the current application in view of the above documents clearly suggesting to the skilled person that campylobacter infections in mammals may be treated using probiotic microorganisms such as Lactobacillus or Bifidobacterium. It is considered that if *Campylobacter* infection was prevented or killed off in the GI tract by any of the compositions defined above, then any shedding and resultant effects would be prevented as a natural consequence of the removal of *Campylobacter* infection in the GI tract. This "shedding" prevention aspect is therefore not a selection from the prior art. Further, the result of administering the composition of the current specification is certainly not unexpected in light of the above prior art - it would be "obvious to try" such a composition against companion mammals in light of the disclosure in the above prior art (see Manual of Patent Practice - Section 3.25).



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[Examination Report contd.]

4. The current specification seeks to differentiate itself from the prior art by the species of animal being treated - in particular by restricting the subject being treated from mammalian animal to companion animal. This restriction does not constitute a technical effect. The technical effects of a second medical use claim are essentially (i) the compound or composition used and (ii) the medical indication being treated.
5. Thus the lack of a technical effect, lack of the criteria for a selection invention and "obvious to try" nature of the subject matter of the claims in view of the above prior art sustain the argument that the present claims still lack an inventive step.